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7011-0032

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **TECH CENTER 1600/2900**

In Re Application of:

Macklin and Fuller

Serial No.: 09/501,328

Group Art Unit: 1641

Filing Date: February 9, 2000

Examiner: Swartz, R.

Title: MYCOBACTERIUM TUBERCULOSIS IMMUNIZATION

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,100,792 issued March 31, 1992 to Sanford et al.;

United States Patent No. 5,219,740 issued June 15, 1993 to Miller et al.;

United States Patent No. 5,630,796 issued May 20, 1997 to Bellhouse et al.;

United States Patent No. 5,714,593 issued February 3, 1998 to Laqueyrie et al.;

United States Patent No. 5,736,524 issued April 7, 1998 to Content et al.;

United States Patent No. 5,865,796 issued February 2, 1999 to McCabe;

International Publication No. WO 88/06591 published September 7, 1988;

International Publication No. WO 90/12875 published November 1, 1990;

International Publication No. WO 96/31613 published October 10, 1996;

International Publication No. WO 98/16646 published April 23, 1998;

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International Publication No. WO 98/31388 published July 23, 1998;

International Publication No. WO 99/04005 published January 28, 1999;

Anderson, Peter, "Effective Vaccination of Mice Against *Mycobacterium tuberculosis* With a Soluble Mixture of Secreted Mycobacterial Proteins," *Infect. Immunity* 62:2536-2544 (1994);

Belisle et al., "Role of the Major Antigen of *Mycobacterium tuberculosis* in Cell Wall Biogenesis," *Science* 276:1420-1422 (1997);

Borremans et al., "Cloning, Sequence Determination, and Expression of a 32-Kilodalton-Protein Gene of *Mycobacterium tuberculosis*," *Infect. Immun.* 57(10):3123-3130 (1989);

Boshart et al., "A Very Strong Enhancer is Located upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell* 41:521-30 (1985);

Calmette et al., "Essais D'Immunisation Contre *L'infection tuberculous*," *Bull. Acad. Natl. Med.* 91:787-796 (1924);

Content et al., "The Genes Coding for Antigen 85 Complexes of *Mycobacterium tuberculosis* and *Mycobacterium bovis* BCG Are Members of a Gene Family: Clonign, sequence Determination, and Genomic Organization of the Gene Coding for Antigen 85-C of *M. Tuberculosis*," *Infectious and Immunity U.S. American Society for Microbiology, Washington* 59(9):3205-3212 (1991);

Horwitz et al., "Protective Immunity Against Tuberculosis Incuced by Vaccination With Major Extracellular Proteins of *Mycobacterium tuberculosis*," *Proc. Natl. Acad. Sci. USA* 92:1530-1534 (1995);

Hubbard et al., "Immunization of Mice With Mycobacterial Culture Filtrate Proteins," *Clin. Exp. Immunol.* 87:94-98 (1992);

Huygen et al., "Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine," *Nature Medicine* 2:893-898 (1996);

Jackson et al., "*Mycobacterium tuberculosis* Des Protein: an Immunodominant Target for the Humoral Response of Tuberculous Patients," *Infection & Immunity* 65(7):2883-2889 (1997);

Kamath et al., "Differential Protective Efficacy of DNA Vaccines Expressing Secreted Proteins of *Mycobacterium tuberculosis*," *Infection and Immunity* 67(4):1702-1707 (1999);

Laqueyrie et al., "Cloning, Sequencing, and Expression of the *apa* Gene Coding for the *Mycobacterium tuberculosis* 45/47-Kilodalton Secreted Antigen Complex," *Infection and Immunity* 63(10):4003-4010 (1995);

Li et al., "Immunogenicity of DNA Vaccines Expressing Tuberculosis Proteins Fused to Tissue Plasminogen Activator Signal Sequences," *Infection and Immunity* 67(9):4780-4786 (1999);

Lotte et al., "BCG Complications: Estimates of the Risks Among Vaccinated Subjects and Statistical Analysis of Their Main Characteristics," *Adv. Tuberc. Res.* 21:107-193 (1984);

Luelmo et al., "BCG Vaccination," *Am. Rev. Respir. Dis.* 125:70-72 (1982);

Oettinger and Anderson, "Cloning and B-Cell-Epitope Mapping of MPT64 from *Mycobacterium tuberculosis* H37Rv," *Infect. Immun.* 62(5):2058-2064 (1994);

Pal et al., "Immunization With Extracellular Proteins of *Mycobacterium tuberculosis* Induces Cell-Mediated Immune Responses and Substantial Protective immunity in a Guinea Pig Model of Pulmonary Tuberculosis," *Infect. Immun.* 60(11):4781-4792 (1992);

Pertmer et al., "Gene Gun-Based Nucleic Acid Immunization: Elicitation of humoral and Cytotoxic T Lymphocyte Responses Following Epidermal Delivery of Nanogram Quantities of DNA," *Vaccine* 13(15):1427-1430 (1995);

Roberts et al., "Characteristics of Protective Immunity Engendered by Vaccination of Mice With Purified Culture Filtrate Protein Antigens of *Mycobacterium tuberculosis*," *Immunology* 85:502-508 (1995); Abstract only;

Rodrigues et al., "Tuberculosis in Developing Countries and Methods for its Control," *Trans. R. Soc. Trop. Med. Hyg.* 84:739-744 (1990);

Tang et al., "Genetic Immunization is a Simple Method for Eliciting an Immune Response," *Nature* 356:152-154 (1992);


Wang et al., "Gene Inoculation Generates Immune Responses Against Human Immunodeficiency Virus Type I," *Proc. Natl. Acad. Sci. USA* 90:4156-4160 (1993);

Wiker and Harboe, "The Antigen 85 Complex: a Major Secretion Product of *Mycobacterium tuberculosis*," *Microbiological Reviews* 56(4):648-661 (1992); and
Young et al., "Dissection of *Mycobacterium tuberculosis* Antigens Using Recombinant DNA," *Proc. Natl. Acad. Sci. USA* 82:2583-2587 (1985).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: Oct 17, 2000

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